



## DEPARTMENT OF HEALTH & HUMAN SERVICES

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Centers for Disease Control and Prevention  
National Center for Health Statistics  
6525 Belcrest Road, Room 1000  
Hyattsville, Maryland 20782

Date: June 1, 2000

From: Raynard S. Kington, MD, PhD  
Director  
National Health and Nutrition Examination Survey  
National Center for Health Statistics/CDC

Subject: Proposal guidelines for the National Health and Nutrition Examination Survey (NHANES) -- Year 2002

To: Potential and Current NHANES Collaborators

Thank you for your interest in submitting a research proposal for the National Health and Nutrition Examination Survey (NHANES) 2002. At this time, NCHS will make only modest changes to the NHANES 2002 protocol. Accordingly, NCHS will consider adding new or revised questionnaire material, a small number of laboratory assessments, and one or two examination components. New examination components are limited to ten minutes in length. Government and non-Government agencies, nonprofit organizations, and private industry are invited to submit research proposals.

The proposal submission process is a 2-stage process. Initially, all proposers should submit a letter of intent describing the proposed NHANES project. The letter of intent should be brief (two pages maximum) and include descriptions of potential issues related to the safety and privacy of survey participants and technical requirements to perform the proposed component in the letter of intent. The due date for the letter of intent is **September 1, 2000**. NCHS will notify proposers if a proposal will be given further consideration by September 30, 2000. Formal research proposals must be received by **October 31, 2000**. Instructions for preparing an NHANES Research Proposal are provided in Attachment 1. Deadlines will be adhered to.

The Program's primary objective in defining the proposal preparation process is to receive concise, well-written proposals that are appropriate for a national health and nutrition survey with an examination component. Prior to submitting your research proposal, we request that you review the NHANES 2000 questionnaires, examination components, and laboratory tests. The current NHANES questionnaires pose a significant respondent burden. In general, the requirements for new questionnaire material are: 1) administration times be limited to no more than one minute, and 2) the information must add significantly to the practical utility of the NHANES data.

NCHS requests that all proposers include funding source information in their proposals. All questions, laboratory analyses, and data collections have costs associated with them. A cost model is used to estimate the marginal costs associated with designing and modifying the automated data collection software, field costs for collecting data, and data preparation and processing. Information is provided to prepare a preliminary cost estimate. In most instances, proposers must guarantee a minimum of three years of financial support for new survey questionnaire and examination component content. Finally, if a new component or set of questions requires pretesting prior to full implementation in the survey, the sponsoring group(s) should be prepared to cover these costs.

To insure receipt of the best possible proposals, we encourage you to contact NCHS with any questions regarding

the requirements of the proposal solicitation process prior to commencing work on the proposal. The NHANES Planning Branch can assist you in preparing your proposal. If you are unfamiliar with the NHANES program, consider a telephone conference call or an informal meeting with NCHS staff to discuss the survey and your research requirements. Joint proposals both within CDC and with other agencies and groups that have similar interests are encouraged. Electronic versions of the NHANES questionnaires, examination components, laboratory tests are available on the NHANES website.

The NHANES research activities website URL is:

**<http://www.cdc.gov/nchs/about/major/nhanes/resrchact.htm>**

The website includes links to survey questionnaires, tables, data files, and proposal solicitation.

Please send all NHANES 2002 proposals to:

Natalie Dupree, M.S.  
National Center for Health Statistics  
Division of Health Examination Statistics  
6525 Belcrest Road, Room 1000  
Hyattsville, MD 20782  
E-mail: [NDupree@cdc.gov](mailto:NDupree@cdc.gov)

We will acknowledge receipt of your letter of intent and research proposal via e-mail. To clarify requirements for the research proposals or to schedule a meeting, please contact Ms. Dupree at 301-458-4196. Ms. Dupree or a member of the Planning Branch staff will contact you.

Again, thank you for your interest in NHANES. If you have further questions, please contact me by telephone: 301-458-4315 or by e-mail: [RKington@cdc.gov](mailto:RKington@cdc.gov).

## **Attachment 1**

### **PROPOSAL GUIDELINES AND FORMATS FOR THE NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY (NHANES) 2002**

#### **What is NHANES?**

The National Center for Health Statistics (NCHS), Division of Health Examination Statistics (DHES), part of the Centers for Disease Control and Prevention (CDC), has conducted a unique series of health and nutrition surveys since the early 1960's. Extensive interview and health examination data are obtained. NHANES were conducted on a periodic basis from 1971 to 1994. NHANES are now conducted on a continuous basis. Each year, approximately 6000 individuals, of all ages, are interviewed in their homes; of these, approximately 5,000 complete the examination component. The health examinations are conducted in mobile examination centers (MECs); a small group of survey participants receives an abbreviated health examination in their homes. NHANES provides an ideal setting for the collection of high quality data in a standardized environment. The target population for NHANES 2002 is the civilian, noninstitutionalized U.S. population. Currently, NHANES over samples low income persons, adolescents 12-19 years, persons 60+ years of age, African Americans and Mexican Americans.

The major objectives of NHANES are:

1. To estimate the number and percent of persons in the U.S. population and designated subgroups with selected diseases and risk factors,
2. To monitor trends in the prevalence, awareness, treatment and control of selected diseases,
3. To monitor trends in risk behaviors and environmental exposures,
4. To analyze risk factors for selected diseases,
5. To study the relationship between diet, nutrition and health,
6. To explore emerging public health issues and new technologies;
7. To establish a national probability sample of genetic material for future genetic research;
8. To establish and maintain a national probability sample of baseline information on health and nutritional status.

#### **How will NHANES research proposals be evaluated?**

Proposals will be evaluated for their relevance to public health issues, for scientific merit, and for technical and methodological feasibility. NCHS will consider the following:

- Are national data needed for this component? Include one or two specific examples of how such national data might be used.
- Why should this component be included in NHANES rather than another data collection modality? What is the added value of collecting the data in a national health examination survey? For example, it is important to describe how interview data can be linked to health outcomes, particularly health outcomes that are measured in the survey.
- Are other sources of national data on this health problem available? If NHANES is the only national survey that can capture the information on this topic, emphasize this point. This is particularly important if your proposal consists solely of questions. Provide information on the scientific validity and reliability of the proposed survey questions in the context of NHANES. Include relevant information on the effects of interview mode or setting on response rates and data quality. For example, if a proposed topic involves sensitive information, be sure to discuss the appropriateness of the planned interview setting and interview mode. Issues related to item non-response and the potential for non-response bias must be addressed.
- What is known about the prevalence of the disease or outcome to be studied? If a health condition or disease is rare in the population (< 5 percent), the proposal should clarify the reasons to include such a component in NHANES.
- Limitations on exam time and concerns regarding respondent burden make it impossible to conduct every component on every participant. It might be necessary to select a subgroup to receive a component. Which age subgroups have the highest priorities for consideration?
- If this component was included in earlier NHANES, explain why it should be repeated in NHANES 2002. For example, if the component is a current public health problem and should be included again for surveillance purposes, describe why NHANES is the appropriate vehicle for data collection. Another example would be to demonstrate the applicability of this component to monitor Healthy People 2010 goals or to establish new health and nutrition priorities.

#### **How much detail should be provided for NHANES research proposals?**

In general, proposals should be both explicit and brief. Be sure to specify the objectives of the component, the design of the research protocol, and the target population. Please provide published reports and articles, including validation studies, expert panel reviews, and study reports from studies that have used the proposed methodology. Details as to the instrument, relevant literature and research, budget, and data collection methods should be included in appendices.

## NHANES Research Proposal Guidelines

The project description (Section 2) should not exceed 10 pages in length. While there is no page limit for the supplementary documents (Section 4), only information that is relevant to the proposal should be included. Each section of the proposal should be paginated separately, with the page number in the bottom center of each page.

Six printed copies of the proposal should be provided to NCHS. In addition, please submit an electronic version of the main proposal sections (on diskette in Word Perfect version 7.0 or higher); printed copies of reference articles and technical materials are acceptable.

### Section 1 Title Page

- Proposal Title
- Abstract
- Table of contents
- Author(s): Please designate a primary contact person
- Institutional affiliation, mailing address, and phone and fax numbers, e-mail address of all authors. (Note: CDC Proposers: Please include CDC Ethics Verification Numbers of CDC investigators.)
- Funding source

### Section 2: Project Description

1. Introduction: Brief history and description of topic area, proposed target population and aims of the proposed research.
2. Public Health Significance

Proposals need to address public health significance in specific terms. The following are examples of relevant topic areas with public health significance. Please address the following, as appropriate:

- a. Surveillance: Is this proposal designed to produce national population health and nutrition parameters? Is the prevalence of this condition known, and/or is the prevalence of this condition expected to change in the future?
- b. Prevention: What significance would this proposal potentially have in the prevention of diseases and their related morbidity and mortality?
- c. Treatment: Will the resulting data be used to assess the effectiveness of treatment or the extent of untreated disease (i.e., awareness, treatment and control of hypertension)?
- d. Health promotion/disease prevention objectives: Would this proposal provide baseline data or be used to assess progress for Healthy People 2010 objectives? If yes, list the objectives and the relevance of the proposed project.
- e. Health policy: How will this proposal address a public health concern that will help decision makers design effective public health programs?
- f. Program evaluation: Will the findings be used to evaluate Federal programs? For example, would this proposal help to assess knowledge, attitudes, practices and progress of health and nutrition

education campaigns, such as: the National Cholesterol Education Program, National High Blood Pressure Education Program, 5-A-Day Initiative, the USDA Supplemental Feeding Program for Women, Infants, and Children (WIC), the Food Stamp Program, Obesity Initiative, Dietary Guidelines for Americans, and food fortification policy initiatives, or other programs?

- g. Health disparities: Will the data be used to assess the health and nutrition status of racial and ethnic minorities and under served populations?

### **Section 3: Data Collection Methods**

Describe the design and methodology of the proposed component including any or all of the following: survey questions, laboratory assays, and examination protocols. If the proposed methods have been used in other major health studies, please provide the names and telephone numbers of the principal investigators; NCHS staff may wish to contact them to discuss the research methods. Please address the following points in the description of the research methodology:

1. Validity and reliability of the methods: Include copies of selected, key journal articles in an appendix section to the proposal. Discuss potential difficulties and limitations of the proposed methods; please provide for new questions, laboratory methods, and examination protocols. For new or revised survey questionnaire items, indicate other surveys or studies that have included the questions; summarize pertinent findings and provide the results of cognitive laboratory research testing; address any issues related to potential differences in the validity and reliability of findings across study subgroups.

Since biologic specimens are required for laboratory assays, please be specific about any non-standard method that is required to collect specimens. The ease of obtaining specimens (especially on the very young), specimen volumes, and specimen storage requirements in the field will be evaluated.

2. Respondent burden. Estimate the time required for a survey participant to respond to the questionnaire items. In the case of examination components, assurance is needed that the total exam will be no longer than ten minutes.
3. Respondent privacy: If the proposed questions or examination contents are sensitive in nature, please propose methods to maintain privacy, minimize embarrassment and reduce item nonresponse.
4. Reporting results: If the results of the laboratory assay or examinations have clinical significance for the SP, describe the ethical issues regarding the reporting the results to the SP. Give us an example of how you would report this finding to the SP. Cite the methods used in other health studies as appropriate. If the results are not to be reported, the rationale for this decision must be justifiable. For questions involving children, specify the age range requiring a proxy/parent respondent; address privacy considerations if a child answers for him/herself.
5. References and citations: Documenting that the proposed methods are well established and capable of being administered in a standardized manner.
6. Target Group: State the gender and age ranges for the proposed component
7. For questionnaire material: Where will the questionnaire and other tests be administered? Specify whether the questions will be part of the household interview or the health examination component. If you are unsure of the content of the current questionnaires, please check with NCHS staff to obtain information about the

NHANES questionnaires.

8. Data analysis, grading, and/or interpretation: How will the data be processed? Specifically, who will perform laboratory analyses, file reading, data scoring, interpretation, and reporting of results? Be sure to specify the proposed laboratory, research group, commercial firm, and so forth. Bottom line: who produces the output data files for this component?
9. Equipment: Brief general description, if applicable. What criteria were used to select the equipment for use in NHANES? Has the equipment been used in other large-scale research studies? Describe the equipment calibration procedures, technician training requirements, and other essential technical requirements.
10. Software: Brief description of the software requirements for specialized instruments. Who has the copyright for the software? Are maintenance agreements and licenses required? What is the cost of the software? Hardware platform requirements should also be described briefly.
11. What is the specificity and sensitivity of the proposed test (laboratory & clinical tests only)?

Number of staff & training for performance in field

Length of time for examination

Quality control requirements

#### **Section 4: Supplementary documents**

##### **1. Laboratory Assays**

- a. Describe the processing required in the field and any time constraints for handling, also the quantity of blood, urine or other laboratory-based specimen required. Laboratory assays should use the least amount of a specimen. Attach specifics of laboratory method in an appendix.
- b. Describe the sensitivity and specificity of the assay and whether it is FDA approved.
- c. Discuss whether the assay is considered 'state-of-the-art' or if it is still developing.

##### **2. Equipment- Please describe the following items if they are applicable to the proposal:**

- a. Equipment maintenance provisions
- b. Safety precautions. Describe subject exclusion criteria, if applicable.
- c. Dimensions of the equipment including weight
- d. Equipment calibration procedures
- e. Daily start-up and shutdown procedures
- f. Portability- Can the equipment be moved several times per year without adverse in mobile trailers without adverse consequences? Has this been done before in other studies?
- g. Describe environmental considerations if applicable. Factors such as temperature, humidity, vibrations, sound, ventilation, voltage, hardware/software, and placement within the mobile exam

center should be addressed.

- h. Equipment manufacturer guarantees, i.e. the availability of maintenance, replacement parts, and possibly replacement equipment to survey sites located throughout the country? Please confirm that the equipment specified for use in the survey will be available for at least three years of survey data collection.
- i. Technical descriptions, manuals, and cost information

## **Section 5: Project Budget**

Please prepare a preliminary budget plan for the proposal. Specify the number of years the project will be undertaken. In most cases, a minimum number of three (3) years of support is required. There are several reasons for this. First, from a data analysis standpoint, three years of NHANES data are required to produce stable national estimates for the population subgroups of interest. Second, considerable development time is required to plan, implement, test, and field survey components. It would not be cost effective to implement new components for less than three years.

All survey collaborators share in the marginal costs associated with including a component in the survey. Annual marginal costs for NHANES 2000 are estimated as follows:

For questions: \$85,000 per minute of interview time (one minute minimum).

For examination components: \$280,000 for up to five minutes of examination time (all age groups; approximately 5,000 individuals per year examined) Examination costs are apportioned according to sample domains for specific components. More information about examination component costs may be obtained from the Planning Branch.

For biological specimen collection: The cost is \$20 per vial of blood, serum, plasma, or urine. Please consult with Planning Branch staff if you require assistance estimating sample sizes. Please note that this cost does not include laboratory analysis costs which must also be funded by the proposer.